

REMARKS

The foregoing amendments to claims 29 and 67 are respectfully submitted in response to the official action dated January 24, 2005, and to correct potential errors in the claims. Thus, the Examiner's attention is specifically directed to Paragraphs [0064] and [0065] on pages 13 and 14 of the substitute specification in which the specific ranges of the variables in the polynomial forms of these claims are set forth, and which now directly correspond to those ranges in claims 29 and 67. It is thus clear that, to the extent that the claims prior to this amendment could be read on polynomials in which each of the eight variables were equal to zero, those claims were read in error, as is shown in the specification and in amended claims 29 and 67. Indeed, there certainly is no intention for the curves represented by these polynomials in both planes perpendicular and parallel to the longitudinal direction of the artificial urinary diversion apparatus hereof to cover straight lines, as suggested by the Examiner. Indeed, the presence of these polynomials in conjunction with the other terms of claim 29 make it abundantly clear that these claims are directed to an artificial urinary diversion apparatus such as that shown in FIGS. 1-5, in which the intermediate or second area includes at least one cross-sectional area which is less than the cross-sectional areas of the first and third areas. In other words, to at least some extent, the intermediate or second area must, as is discussed in the specification, define a constriction which makes it possible, for example, for arteries to be led laterally past the side surface 9 (see, for example, Paragraph [0057], pp. 12-13). It is, in any event, believed that the present claims are clearly patentable over the art, and the reasons therefor will now be set forth in detail.

Claims 29, 67 and 68 have been rejected as being anticipated by Guiset. Guiset is said to disclose an artificial urinary diversion system comprising a urinary bladder 1 with an axial direction comprised of three portions, the Examiner referring to reference numerals 20 for the lowest point, 5 for the middle area, and 30 for the topmost portion. The first and second portions are said to be smaller in cross-section than the upper portion, and the first portion is said to comprise an outlet 4 and sphincter mechanism 18 to open and close at least one outlet to expel liquid contained within chamber 1, and the third portion includes inlet 3 and sphincter mechanism 17 for opening and closing the sphincter. The third portion is said to comprise a second inlet in the area of reference numeral 28, and the sphincter mechanism is referred to as an anti-reflux valve such as a Bjork-type valve or STARR-valve. This device is said to inherently have a three-dimensional shape capable of containing a volume of fluid and therefore would have a plurality of cross-sectional areas if divided up into portions. The Examiner then concludes that Guiset's device may have a cylindrical shape, citing column 4, lines 59-66, and would therefore allegedly suit the function recited in claim 29 if the values for  $a_1$ - $a_6$  were all equal to zero. The Examiner concludes that the cylinder would have a first outline having a shape of a straight line in the plane parallel to the longitudinal direction, and the other side of the cylinder would provide a second outline having a shape of a straight line in a plane parallel to the longitudinal direction. This rejection is respectfully traversed in view of the above amendments and arguments and for the reasons set forth hereinafter.

Turning first to the Guiset reference itself, this patent does relate to an artificial bladder which can be substituted for a bladder when required. The device shown in

Guiset thus includes a closed cavity 2 which, while including an upper aperture 3 for connection to the ureter and a lower aperture 4 for connection to the urethra, is "preferably of a pseudo-pyramidal shape related to that of a natural bladder so that it can be implanted into the space normally occupied by the bladder." That shape is shown in FIG. 1, and certainly does not meet the most basic requirements of claim 29; namely, a second or intermediate area which includes at least one cross-sectional area which is less than the cross-sectional area of the first or lower area. To the contrary, there is no intermediate constriction whatsoever in the device in Guiset, which enlarges from bottom to top in a gradual and continuous manner.

Secondly, the device shown in Guiset, while including a sphincter mechanism for opening and closing the outlet and a control means for controlling the sphincter mechanism, does so in a manner which is quite different from that anticipated by applicants. Thus, in accordance with this disclosure, direct control of the sphincter mechanism in the upper or inlet portion of the device is by a reservoir 23 of fluid 24 separate and apart from the artificial urinary diversion apparatus claimed herein. This reservoir 23, as shown in FIG. 1, includes a flexible zone 26 which can receive an impulse from the outside for transmission to fluid 24 in order to expel that fluid towards chamber 21 of sleeve 15 to cause the upper sphincter mechanism to close. No specific device is provided for inducing the lower aperture 4 to open, but instead since the chamber 22 of collar 16 is filled with fluid at a fixed pressure, it can be opened when the pressure in cavity 2 increases above a predetermined threshold following an impulse on flexible zone 26 of reservoir 23. Thus, fluid 24 in this instance will flow into a small balloon 27 within the device creating such additional

pressure. This, in turn, will presumably open the lower sphincter.

The Examiner has attempted to apply Guiset to the claims by referring to column 4, lines 59-66 thereof, and claiming that the device in Guiset can have a cylindrical shape. Firstly, the portion of the Guiset specification referred to by the Examiner does not relate to the shape of the cavity 2 for the urinary or artificial bladder device of that patent, but it specifically refers to the shape of reservoir 23, which is separated and external thereto. Thus, the specification states that, with respect to the reservoir, it can be replaced by a cylindrical cavity. When discussing the urinary device itself, however, it is believed by this patentee to be important to only employ the pseudo-pyramidal shape, because it is said to relate to the natural bladder.

The present invention is quite different from Guiset. It is thus intended to be applicable to the body shapes and functions of different patients, and for that reason includes the limitations now set forth in these claims. In addition, it is again noted that the claims are not directed to a polynomial which can lead to a straight line, or in which all of the "a" variables can be zero, as suggested by the Examiner. Referring back to the specification in this regard, it will be clear, particularly referring to FIGS. 9 and 10, that these polynomials are specifically directed to the type of shape to which the remainder of claim 29 is directed, including one in which the intermediate portion includes a narrower portion than either of the other two portions thereof.

It is therefore respectfully submitted that the claims in this application clearly distinguish in a patentable manner over the prior art, including Guiset. In view thereof,

reconsideration and allowance of these claims is respectfully solicited. If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that the Examiner telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have to the immediate allowance of this application.

Finally, if there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: July 6, 2005

Respectfully submitted,

By 

Arnold H. Krumholz

Registration No.: 25,428

LERNER, DAVID, LITTENBERG,

KRUMHOLZ & MENTLIK, LLP

600 South Avenue West

Westfield, New Jersey 07090

(908) 654-5000

Attorney for Applicant